REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claim Amendments

Claims 8 and 10 have been amended to replace the transitional phrase "consisting essentially of" with --consisting of--.

New claims 11 and 12 have been added to the application. Support for new claim 11 can be found in Examples found in the specification, and support for new claim 12 can be found in the specification on page 9, lines 6-14.

Patentability Arguments

The patentability of the present invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Rejection Under 35 U.S.C. § 103(a)

Claims 8 and 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kurokawa et al. (JP 07118161) in view of Fujimaki et al. (JP 63239228), Nakamura (JP [2000281562]), Ninomiya et al. (US 5932235), Aoi et al. (JP 04346937), Okudaira et al. (JP 09286735), and Inoue et al. (WO 00/24273, with US 2007/0212460 as translation).

This rejection is respectfully traversed for the following reasons.

The Position of the Examiner

Initially, the Examiner takes the position that, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising". Thus, the Examiner has interpreted the claims as reading "comprising".

Further, the Examiner takes the position that Kurokawa et al. teach anti-viral agents with a Chinese medicated mixture named Kakkonton, where no agar or phosphates are present. The Examiner acknowledges that Kurokawa et al. fail to teach Sho-saiko-to, less than 60% w/w per total composition, 0.01-10.0 w/w% of carrageenan, carob bean gum, and xanthan gum.

The Examiner states that Fujimaki et al. teach treatment for a person infected with a virus with Chinese medicine Shosaikoto.

The Examiner states that Nakamura et al. teach a gel composition comprising a water soluble drug in carrageenan, locust bean gum and xanthan gum.

The Examiner states that Ninomiya et al. teach a medical composition for oral administration, which is formulated into a jellied form using a base containing carrageenan and locust bean gum.

The Examiner states that Aoi et al. teach a simple and economical way to reduce bitterness of drugs, such as Shosaikoto with gelatinizing agents.

The Examiner states that Okudaira et al. teach agents to improve the bad taste of kakkon-to.

Regarding concentration, the Examiner states that Inoue et al. teach Chinese medicine formulations including Kakon-to and Sho-saiko-to as oral composition of jellies made with hydrocolloids.

The Examiner takes the position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to [make] a composition with Kakkon-to and Sho-saiko-to because these medicines are used against viruses. Further, the Examiner contends that, absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

Applicants' Arguments

Applicants' amended claim 8 requires a Chinese herbal medical composition in the form of jelly, consisting of a Chinese herbal medicine in a base,

wherein the Chinese herbal medicine is selected from the group consisting of Kakkon-to and Sho-saiko-to, and is present in an amount less than 60 w /w% per total amount of the composition,

wherein the base consists of 0.01 to 10.0 w /w% carrageenan, 0.01 to 10.0 w/w% carob bean gum and 0.01 to 10.0 w/w% xanthan gum, per total amount of the composition, and

wherein the base does not include a phosphate buffer or agar.

As discussed in detail in the previous responses, the Chinese herbal medical composition of Applicants' claims unexpectedly improves syneresis, and is unexpectedly superior in long term preservative stability.

Initially, Applicants respectfully disagree with the basis of the Examiner's rejection. Specifically, none of the cited references teach or suggest the specific combination set forth in Applicants' claims, i.e., Kakkon-to or Sho-saiko-to in a base consisting of the particularly recited amounts of carrageenan, carob bean gum and xanthan gum.

As will be discussed in detail below, each of the references relied upon by the Examiner lacks at least one required aspect of Applicants' composition, or includes a component which is excluded by Applicants' claims.

The Examiner appears to take the position that merely because each of Applicants' recited components is known in the art, it would obvious to combine them in the amounts specifically recited by Applicants'. However, Applicants kindly assert that this rejection can only be based upon hindsight, as **none** of the references, nor any combination thereof, provides motivation to create Applicants' specific composition, with any reasonable expectation of success.

As the Examiner is certainly aware, a rejection based upon hindsight is improper, and should be avoided. Specifically, as stated by the Supreme Court in KSR International Co. v. Teleflex Inc., "the factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." (See KSR International Co. v. Teleflex Inc., 237 S. Ct. 1727 (U.S. 2007), referring to Graham v. John Deere Co. of Kansas City, 86 S. Ct. 684, which warned against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "guard against slipping into the use of hindsight".

Furthermore, Applicants clearly delineate how each of the references relied upon by the Examiner is deficient, by failing to (1) teach or suggest each of the required limitations, or (2) provide any reason to combine the particular limitations.

Further still, the Examiner states that **absent evidence to the contrary**, the composition is obvious. Applicants respectfully remind the Examiner that evidence of unexpected results has previously been provided. Specifically, the Declaration submitted with the response filed April 16, 2007 demonstrates:

(1) A combination of κ-carrageenan, carob bean gum and xanthan gum greatly improved syneresis compared to a composition using only κ-carrageenan.

(2) A combination of κ-carrageenan, carob bean gum and xanthan gum drastically improved syneresis compared to a composition using only carrageenan and carob bean gum.

Thus, Applicants **have** provided a showing of unexpected results, which demonstrates that the claimed composition is not obvious.

The Kurokawa et al. patent relates to an antiviral agent, which has a low side action by using Kakkon-to as an active component. However, as admitted by the Examiner, the agent does not contain carrageenan, carob bean gum or xanthan gum. Thus, this reference merely demonstrates that Applicants' recited Chinese herbal medicines are known in the art. Applicants have not disputed this fact. However, the reference provides no motivation for combining this particular active in a base consisting of carrageenan, carob bean gum and xanthan gum, in the particular amounts required by Applicants' claims.

The Fujimaki et al. patent relates to an immune-activating agent for a person infected by a virus of acquired immune deficiency syndrome (AIDS), where the agents contain a Chinese medicine Sho-saiko-to. However, this agent also fails to comprise carrageenan, carob bean gum or xanthan gum. Thus, similar to the discussion regarding Kurokawa et al., this reference merely demonstrates that Applicants' recited Chinese herbal medicines are known in the art. This reference also fails to provide any motivation for combining this particular active in a base consisting of carrageenan, carob bean gum and xanthan gum, in the particular amounts required by Applicants' claims.

As explained previously (in the response filed April 16, 2007), the Ninomiya et al. patent relates to a jellied medical composition for oral administration, which is easily taken by patients of advanced age or patients with dysphagia. The base of the jelly of Ninomiya et al. contains carrageenan and locust (carob) bean gum, and preferably further contains polyacrylic acid or a

partly neutralized product or a salt thereof. However, the reference fails to even mention the Chinese herbal medicines required by Applicants' claims.

Ninomiya et al. describe that as a base used in a jellied medical composition for oral administration, one or more selected from gelatin, pectin, xanthan gum, carrageenan, locust bean gum, mannan, etc., may be used, and the base containing carrageenan and locust bean gum is preferable. However, in the examples, only a combination of κ-carrageenan and locust bean gum is used.

On the other hand, Applicants' claimed composition requires a Chinese herbal medical composition in the form of jelly, wherein a Chinese herbal medicine is contained in a base consisting of carrageenan, carob bean gum and xanthan gum. The base of Applicants' claimed composition does not include polyacrylic acid or a partly neutralized product or a salt thereof. In fact, the "consisting of" language of Applicants' claims excludes these additional components.

Furthermore, as discussed above, Comparative experiment B of the Declaration submitted April 16, 2007 demonstrates that when a combination of κ-carrageenan, carob bean gum and xanthan gum is used, the syneresis is drastically (unexpectedly) improved, compared with a combination of only carrageenan and carob bean gum.

The Aoi et al. patent relates to a method for reducing the bitterness of bitter and not-readily-ingestible substances often existing in drugs and foods, by preparing a seasoned jelly by mixing a bitter substance with a gelatinizing agent and a seasoning agent. As a gelatinizing agent, agar, gelatin, κ-carrageenan, etc. are described. However, there is no teaching or suggestion of the particular combination of carrageenan, carob bean gum and xanthan gum in a base, nor the advantageous and unexpected effects resulting therefrom.

Furthermore, as discussed previously, Comparative experiment A of the Declaration filed April 16, 2007 demonstrates that when a combination of κ-carrageenan, carob bean gum and xanthan gum are used, the syneresis is considerably improved, compared with only κ-carrageenan.

The Okudaira et al. patent relates to an extract of Kakkon-to containing stebioside for improving bad taste. However, the extract does not contain carrageenan, carob bean gum or xanthan gum. Accordingly, similar to the discussion of the first two cited references, this reference merely demonstrates that Applicants' recited Chinese herbal medicine is known in the

art. The reference fails to provide any motivation for combining such a medicine in the particular base required by Applicants' claims.

Regarding the Inoue et al. reference, Applicants kindly refer the Examiner to pages 4-11 of the response filed September 22, 2008, where the reference is discussed in detail. As a brief summary, Applicants respectfully assert that the teachings of Inoue et al. are quite distinct from Applicants' claimed composition, in that Inoue et al. relates to the use of sucralose in many difference manners.

Regarding Nakamura et al. (JP 2000-281562), Applicants clarify that this reference is different from the one cited in the third line of the rejection on page 3 of the Office Action. The Examiner clarified the reference number during a telephone call with Applicants' representative.

Applicants submit herewith a full translation of the Nakamura et al. patent.

The Nakamura et al. patent relates to a gel-like composition containing **a water-soluble medicine**, vegetable polymer gelling agent(s), **a sugar alcohol**, and water. As the **water-soluble medicine**, lysozyme chloride, bromohexine hydrochloride or cyanocobalamin are illustrated. [These medicines are water-soluble, i.e., 1g/100mL or more at 25°C.]

As the vegetable polymer gelling agents, a combination of carrageenan, carob bean gum and xanthan gum is illustrated.

However, there is no teaching or suggestion in the reference to use any Chinese medicine, such as Kakkon-to or Sho-saiko-to. As shown in Example 1 of the Nakamura et al. patent, a drug such as lysozyme chloride is dissolved in water to prepare an aqueous solution, and then the mixture containing other ingredients is mixed at about 60°C with the solution to prepare the desired gel-like composition. In other words, an aqueous solution containing a **water soluble drug** is made into a gel-like composition containing the drug in its stable state (without inactivation) by adding a **sugar alcohol** as a sweetener.

The problem to be solved in Nakamura et al. is to provide a gel-like sweet composition containing the water-soluble drug and the vegetable polymer gelling agents, without affecting the activity of the drug. The reference solves this problem by using **a sugar alcohol instead of sucrose** as a sweetener.

On the contrary, the objective of Applicants' composition is to achieve a composition comprising a Chinese herbal medicine in a jelly form, wherein the composition hardly causes

syneresis in long term preservation. Chinese herbal medicines, such as Kakkon-to or Sho-saiko-to, are **not very soluble in water**, especially at room temperature, e.g., 25°C. Rather, Chinese herbal medicines are generally dispersible in water, because they are not single compounds and are composed of various ingredients (compounds). Furthermore, as Chinese medicines are usually administered in a larger amount to the patient, the preparation must contain a larger amount of the Chinese medicine, e.g., 14-30g/100ml.

According to Nakamura et al., when a water-soluble drug, such as bromohexine hydrochloride, is gelled, and sucrose is added thereto, the drug is inactivated. (Please see paragraphs [0004] and [0005] of the attached English translation.) Furthermore, lysozyme chloride is also inactivated by adding sucrose as shown in table 1 of the patent.

On the contrary, the jellied composition of Applicants' claims is not affected by adding sucrose, or sugar alcohols, such as sorbitol. Specifically, as discussed on page 7 of Applicants' substitute specification, sweetening agents such as sucrose and sorbitol may be added to the composition.

Furthermore, in the teachings of Nakamura et al., a water soluble compound (a single compound) is completely dissolved in water, and the solution is made by adding the gelling agents in a jelly form. With this type of preparation, it is not necessary to address syneresis (separation of water). This is clearly demonstrated in Table 2 of the Nakamura et al. patent. Thus, not only does Nakamura et al. fail to teach Applicants' required Chinese herbal medicine, but the objective of Applicants' invention would not even be considered from the teachings of the reference.

Since the problems to be solved by the references are so distinct, a person of ordinary skill in the art would never have been motivated to combine the teachings of Nakamura and the other cited art, such as Kurokawa, to achieve Applicants' claimed composition, which achieves the afore-mentioned unexpected results.

Further still, Nakamura et al. fail to teach or suggest that any other components (other than water-soluble compounds) are stably gelled by adding the gelling agents in a combination of carrageenan, carob bean gum and xanthan gum. Also, one of ordinary skill in the art would not have been motivated to apply the teachings of the Nakamura patent to Chinese herbal medicines such as Kakkon-to or Sho-saiko-to, because the subjects to be stabilized (the active agents) are

too distinct.

Therefore, even if the vegetable polymer gelling agents (carrageenan, xanthan gum and locust bean gum) are the same in the Applicants' claims, and in the Nakamura patent, the skilled person would not be motivated to combine the teachings of Nakamura et al. with Applicants' particularly recited active agents, absent the teachings of Applicants' specification. In particular, the water soluble drugs of Nakamura et al. are quite distinct from the active agents recited in Applicants' claims. The Examiner's general assertion that one could merely substitute the Chinese herbal medicines for the water soluble drugs of Nakamura et al. would lead one to believe that any active agent could be substituted for any other active agent in a pharmaceutical system. Such a broad and generalized assertion cannot be considered proper.

Applicants' jelly preparation containing a Chinese herbal medicine (Kakkon-to or Sho-saiko-to) hardly causes syneresis, is superior in long term preservative stability and is orally taken without taking care of bitter. This invention would not have been obvious to one of ordinary skill in the art based upon the teachings of the references relied upon by the Examiner.

Thus, it is evident that the subject matter of Applicants' claims is patentable over the cited combination of references. It is respectfully requested that the above-rejection be withdrawn.

Conclusion

Therefore, in view of the foregoing amendments and remarks, it is submitted that the ground of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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